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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,182	07/11/2001	Albert C. Lardo	56245	1162

21874 7590 06/05/2006
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BOSTON, MA 02205

EXAMINER

SHAY, DAVID M

ART UNIT PAPER NUMBER

3735

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,182

Applicant(s)

LARDO

Examiner

david shay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on April 12 2006
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 12, 2006 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant appears to argue that because Motamedi teaches the ablation of deep tissue in the myocardium, this teaching cannot be used to teach ablation of tissues on the surface. This argument is flawed in that Motamedi (in addition to the discussion of PDT as set forth in the previous response and which is incorporated herein by reference), specifically teaches that the invention described therein as a "device that is used to deliver light superficially..." Thus clearly Motamedi teaches the superficial as well as the deep application of light for PDT. It is also noted that a recognized treatment of arrhythmia is the ablation of the tissue which is causing the arrhythmia, be it deep or superficial.

Claims 61-63 and 78-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motamedi in combination with Swanson and Altman. Motamedi teaches employing various methods, including photodynamic therapy to destroy tissue which causes arrhythmias. Swanson teaches that various means can be used to destroy tissue which causes arrhythmias; that determining the tissue to be ablated by stunning the tissue and seeing if the arrhythmia stops; and that various methods may be employed to locate the treatment device at the site. Altman teaches ablating to isolate the pulmonary vein to treat arrhythmia. It would have been obvious to the

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artisan of ordinary skill to employ the phototherapeutic treatment of Motamedi in the method of Swanson or to employ the guidance technique of Swanson, which can include MRI; the energy application, which can include transmission of the tissue destroying energy through intervening media in contact with the tissue, to which the energy is essentially transparent; and the application to atrial fibrillation in the method of Motamedi, and in either case to ablate the tissue which, when inhibited, stops the arrhythmia, such as the pulmonary vein, as taught by Altman, and to administer the photosensitizer via perfusing the coronary arteries, or by intravenous injection, since these are not critical; do not require site specific administration of the photosensitizer; and provide no unexpected result, and since Motamedi provides no particular delivery method, thus producing a method such as claimed.

Claims 64-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motamedi in combination with Swanson and Altman as applied to claims 61-63 and 78-81 above, and further in combination with Leone. Leone teaches a porous balloon for delivering a photodynamic therapy substance which is also injected with saline. It would have been obvious to the artisan of ordinary skill to use a porous balloon to deliver the photodynamic therapy substances in the method of Motamedi et al, since Motamedi et al provide no particular delivery method, and to insert the fiber into the balloon prior to the balloon being placed in the vein ostia, since this is not critical, would ensure that the fiber is properly located within the balloon, and provides no unexpected result; to apply a point or linear source of light, since these are well known irradiation patterns; would provide greater control over light application; and provides no unexpected result, thus producing a method such as claimed.

Claim 82 is rejected under 35 U.S.C. 103(a) as being unpatentable over Motamedi in combination with Swanson and Altman as applied to claims 61-63 and 78-81 above, and further in combination with Rice et al. Rice et al teach that phthalocyanines are appropriate photosensitizers. It would have been obvious to the artisan of ordinary skill to employ phthalocyanines as the photosensitizers, since these are effective as photosensitizers and Motamedi teaches no particular photosensitizer, thus producing a method such as claimed

Applicant's arguments with respect to claims 20-29, 31-41, 48-50, 58, and 59 have been considered but are moot in view of the new ground(s) of rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 61-82 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6-17, 19-26, 28-45, 47, 49, 51, 53-55, and 57 of U.S. Patent Application Serial No. 09/796,571. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application claims are not patentably distinct from the patent claims. Here, the patent claims require

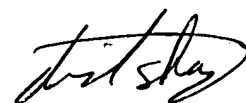
elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in *In re Goodman* cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID M. SHAY
PRIMARY EXAMINER
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